Supreme Court U.S.
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No. _____

In the Supreme Court of the United States

PEDIATRIC SPECIALTY CARE, INC., et al.,
Petitioners,

v.

ARKANSAS DEPARTMENT
OF HUMAN SERVICES, et al.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether federal law prohibits a peer review organization from disclosing the identity of doctors and nurses who have denied payment for medical services to a Medicaid-eligible individual on the basis of medical necessity where the individual seeks the identity of the doctors and nurses in connection with an administrative appeal of the decision to deny payment for the services in question.

PARTIES TO THE PROCEEDING

Petitioners

- Pediatric Specialty Care, Inc.
- Child & Youth Pediatric Day Clinics, Inc.
- Family Counseling & Diagnostic Clinic, Inc.
- Tomorrow's Child Learning Center, LLC
- D & D Family Enterprises, Inc.
- James and Stacey Swindle, as parents and next friends of Jacob and Noah Swindle, minors
- Susann Crespino, as parent and next friend of Michael Crespino, a minor

Respondents

- Arkansas Department of Human Services
- Ray Hanley, in his individual capacity
- Roy Jeffus, in his individual capacity and in his official capacity as Director of the Division of Medical Services of the Arkansas Department of Human Services
- Arkansas Foundation for Medical Care, Inc.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of the Supreme Court of the United States, the petitioners make the following disclosures:

1. Petitioner Pediatric Specialty Care, Inc. ("PSC") is a corporation created under Arkansas law. PSC is wholly-owned by Ascent Acquisition Corporation ("AAC"), which is wholly-owned by Youth & Family Centered Services, Inc. ("YFCS"). No publicly-held corporation owns any part of its stock.

2. Petitioner Child & Youth Pediatric Day Clinics, Inc. ("CYPDC") is a corporation created under Arkansas law. CYPDC is wholly-owned by AAC, which is wholly-owned by YFCS. No publicly-held company owns any part of its stock.

3. Petitioner Family Counseling & Diagnostic Clinic, Inc. ("FCDC") is a Subchapter S corporation created under Arkansas law. FCDC has no parent corporation, and no publicly-held company owns any part of its stock.

4. Petitioner Tomorrow's Child Learning Center, LLC ("TCLC") is a limited liability corporation created under Arkansas law. TCLC has no parent corporation, and no publicly-held company owns any part of its stock.

5. Petitioner D & D Family Enterprises, Inc. ("D & D") is a Subchapter S corporation created under Arkansas law. D & D has no parent corporation, and no publicly-held company owns any part of its stock.

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OPINIONS AND ORDERS BELOW

The order of the United States Court of Appeals for the Eighth Circuit dated June 22, 2006, denying the petition for rehearing or rehearing en banc was not officially reported and is reproduced at Appendix A at 1a.

The opinion of the United States Court of Appeals for the Eighth Circuit dated April 17, 2006, reversing the opinion of the District Court is officially reported at 444 F.3d 991 and is reproduced at Appendix B at 2a.

The opinion of the United States District Court for the Eastern District of Arkansas dated November 29, 2004, granting injunctive relief to the petitioners was not officially reported and is reproduced at Appendix C at 10a.

JURISDICTION

The opinion of the United States Court of Appeals for the Eighth Circuit sought to be reviewed was entered on April 17, 2006. This petition is timely under 28 U.S.C. § 2101 and Supreme Court Rule 13.1 because it is being filed within 90 days after the entry of the opinion of the United States Court of Appeals for the Eighth Circuit denying rehearing and rehearing en banc entered on June 22, 2006. This Court has jurisdiction to review the opinion of the United States Court of Appeals for the Eighth Circuit pursuant to 28 U.S.C. § 1254.

STATUTES AND REGULATIONS INVOLVED

This petition involves provisions of the Peer Review Improvement Act of 1982, specifically 42 U.S.C. §§ 1320c-3, 1320c-5, and 1320c-9, which are set forth in Appendix D at

27a, and 42 C.F.R. § 480.101, which is set forth in Appendix E at 46a.

STATEMENT OF THE CASE

The Arkansas Department of Human Services ("ADHS") is charged with administration of the Medicaid program in Arkansas. In Arkansas, the State Medicaid Plan ("State Plan") includes services provided under the Child Health Management Services ("CHMS") program. ADHS contracts with Arkansas Foundation for Medical Care, Inc. ("AFMC") to provide prior authorization for CHMS services. If AFMC refuses to authorize CHMS services requested on behalf of a Medicaid-eligible child, the child's parent or guardian may appeal the adverse decision in accordance with the Arkansas Administrative Procedure Act, Ark. Code Ann. §§ 25-15-201 to 218 ("APA").

On July 23, 2003, the petitioners filed a Second Amended Complaint in which they added AFMC to this litigation, and alleged that ADHS and AFMC have violated, and continue to violate, the Medicaid Act, GET, by refusing, when requested during the pre-hearing course of an administrative appeal, to identify the nurses and doctors who made the adverse decision at issue on appeal. By filing this claim, the petitioners sought to challenge the refusal of ADHS and AFMC to disclose this information on the grounds that it violates the fair hearing provision of the Medicaid Act, 42 U.S.C. § 1396a(a)(3). Jurisdiction of the District Court was invoked pursuant to 28 U.S.C. § 1331.

On February 27, 2004, petitioner Tomorrow's Child Learning Center ("Tomorrow's Child") filed a Motion for Temporary Restraining Order in which it requested an injunction that requires ADHS and AFMC, among other

things, to identify the nurses and doctors who deny CHMS services when such information is requested during the pre-hearing course of an administrative appeal. The District Court held a hearing with respect to this motion, and issued an order on May 28, 2004, in which it held that the federal statutes and regulations cited by ADHS and AFMC protected disclosure of the requested information.

Thereafter, on July 7, 2004, the petitioners filed a Fourth Amended Complaint in which they added a new claim that attacks the constitutionality of the federal statutes and regulations relied upon by the District Court in its order dated May 28, 2004. On November 29, 2004, the District Court issued a decision that reversed its ruling dated May 28, 2004, and held that the federal statutes and regulations asserted by ADHS and AFMC in support of their claim of privilege do not protect the identities of the doctors and nurses who review CHMS services on their behalf. In addition, the District Court ruled that the federal regulations relied upon by ADHS and AFMC were invalid because they were issued by the Secretary of Health and Human Services ("the Secretary") outside the scope of rulemaking authority granted by Congress in 42 U.S.C. § 1320c-9(a)(2).

ADHS and AFMC appealed the District Court's ruling. The Court of Appeals reversed the District Court based on 42 C.F.R. § 480.101, which deems as confidential information that "explicitly or implicitly identifies an individual patient, practitioner, or reviewer". In reversing the District Court on this issue, the Court of Appeals did not explain why it disagreed with the conclusion made by the District Court that the Secretary was not authorized by Congress to issue the regulation in question.

REASONS FOR GRANTING THE PETITION

The primary statute at issue in this case is 42 U.S.C. § 1320c-9(d). ADHS and AFMC asserted this statute as the basis of their claim that the identity of the nurses and doctors who prior authorize CHMS services is prohibited from disclosure under federal law. The District Court held that 42 U.S.C. § 1320c-9(d) is not ambiguous, and does not create a privilege with respect to the identity of the doctors and nurses who deny authorization for CHMS services based on grounds of medical necessity.

The District Court was correct in determining that the meaning of § 1320c-9(d) is clear. As the District Court explained in its opinion, the first sentence of § 1320c-9(d) does not protect the disclosure of "reviewer identity" because it only applies to "patient records". The names of nurses and doctors who deny payment in a particular case are not "patient records", and the first sentence makes no reference to the identity of the reviewers. For these reasons, the first sentence of § 1320c-9(d) does not create a privilege that protects the identity of the nurses and doctors at issue in this case.

The second sentence of § 1320c-9(d) does not create such a privilege either. By its terms, the second sentence only prohibits the disclosure of information referred to in 42 U.S.C. § 1320c-3(a)(1)(B) and 42 U.S.C. § 1320c-5(a)(2). Section 1320c-3(a)(1) has three subparts, the first and third of which relate to information gathered for purposes of determining medical necessity. The second subpart, § 1320c-3(a)(1)(B), relates to information gathered for purposes of determining quality of care. Congress included only the second subpart within the scope of the privilege. It could

have included the subparts relating to medical necessity but did not do so.

The same can be said with respect to 42 U.S.C. § 1320c-5(a), which also has three subparts. The first and third of its subparts relate exclusively to medical necessity, and the second subpart, § 1320c-5(a)(2), relates exclusively to quality of care. Congress included the subpart regarding quality of care within the scope of the privilege, but did not include the other two subparts within the privilege. As the District Court stated in its opinion, where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion. INS v. Cardoza-Fonseca, 480 U.S. 421, 432 (1987).

No other information is prohibited from disclosure by § 1320c-9(d), and ADHS and AFMC relied upon no other statute in support of their position that reviewer identity is protected from disclosure under federal law. Instead, they relied on a handful of federal regulations issued by the Secretary of Health and Human Services ("the Secretary") pursuant the congressional grant of rulemaking authority set forth in § 1320c-9. Congress has, in this statute, authorized the Secretary to promulgate regulations "to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care." 42 U.S.C. § 1320c-9(a)(2).

Of the regulations cited by ADHS and AFMC, the Court of Appeals based its opinion on 42 C.F.R. § 480.101. This regulation sets forth a number of definitions used throughout the series of subsequent regulations, and includes a definition of the term "confidential information". According to this

definition, "confidential information" includes any "[i]nformation that explicitly or implicitly identifies an individual patient, practitioner or reviewer." 42 C.F.R. § 480.101(b) (emphasis added). The District Court recognized that this regulation expands the breadth of the statutory privilege by including reviewer identity within its terms. Noting that Congress did not include reviewers as beneficiaries of the grant of rulemaking authority set forth in § 1320c-9(a)(2), the District Court concluded that the Secretary did not have the authority to issue this regulation.

In reaching its decision, the District Court cited Public Citizen, Inc. v. United States Dept. of Health and Human Serv., 332 F.3d 654 (D.C. Cir. 2003), in which the circuit court held that "§ 1320c-9(a)(2) does not permit the Secretary to impose his own nondisclosure requirements; rather, it authorizes the Secretary to promulgate regulatory exceptions to the general nondisclosure requirement." Id. at 664. Based on the clear terms of § 1320c-9(a)(2), the Secretary did not have authority under that statute to promulgate a regulation like § 480.101 that advances the interests of reviewers to the detriment of persons Congress intended to protect.

This Court stated in Manhattan Gen. Equip. Co. v. Commissioner of Internal Revenue, 297 U.S. 129 (1936), that:

> The power of an administrative officer or board to administer a federal statute and to prescribe rules and regulations to that end is not the power to make law – for no such power can be delegated by Congress – but the power to adopt regulations to carry into effect the will of Congress as expressed by the statute. A regulation which does not do this, but operates to create a rule of out of harmony with the statute, is a

> mere nullity. And not only must a regulation, in order to be valid, be consistent with the statute, but it must be reasonable.

Id. at 134 (emphasis added)(internal citations omitted). Because the Secretary did not have the authority to issue § 480.101, the regulation is a nullity and the opinion expressed by the Court of Appeals must fail. The Court of Appeals should not have considered this regulation in deciding this case, and erred in reversing the District Court on this issue. The Supreme Court should grant certiorari to resolve this issue which is of extreme public importance to Medicaid recipients, providers, and practitioners alike.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 05-1115, No. 05-1116

[Filed June 22, 2006]

Pediatric Specialty Specialty Care, Inc., et al.,	)
	)
Appellees,	)
	)
v.	)
	)
Arkansas Foundation for Medical Care,	)
	)
Appellants.	)
	)

Order Denying Petition for Rehearing and for Rehearing En Banc

The petition for rehearing en banc is denied. The petition for rehearing by the panel is also denied.

June 22, 2006

Order Entered at the Direction of the Court:

Clerk, U.S. Court of Appeals, Eighth Circuit

APPENDIX B

UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

No. 05-1115, No. 05-1116

[Filed April 17, 2006]

Pediatric Specialty Care, Inc.; Child & Youth Pediatric Day Clinics, Inc.; Family Counseling & Diagnostic Clinic; Tomorrow's Child Learning Center, LLC; D&D Family Enterprises, Inc.; James Swindle; Stacey Swindle, as parents and next best friends of Jacob and Noah Swindle, Minors; Susann Crespino, as parent and next best friend of Michael Crespino, a minor;

Plaintiffs-Appellees,

v.

Arkansas Department of Human Services; Kurt Knickrehm, in his individual capacity and in his official capacity as Director of the Arkansas Department of Human Services; Ray Hanley, in his individual capacity as Director of the Division of Medical Services of The Arkansas Department of Human Services;

Defendants,

Arkansas Foundation for Medical Care;

Defendant-Appellant,

Roy Jeffus, in his official capacity as Interim Director of Arkansas Department of Human Services Division of Medical Services;

Defendant.

Pediatric Specialty Care, Inc.; Child & Youth Pediatric Day Clinics, Inc.; Family Counseling & Diagnostic Clinic; Tomorrow's Child Learning Center, LLC; D&D Family Enterprises, Inc.; James Swindle; Stacey Swindle, as parents and next best friends of Jacob and Noah Swindle, Minors; Susann Crespino, as parent and next best friend of Michael Crespino, a minor;

Plaintiffs-Appellees,

v.

Arkansas Department of Human Services; Kurt Knickrehm, in his individual capacity and in his official capacity as Director of the Arkansas Department of Human Services; Ray Hanley, in his individual capacity as Director of Division of Medical Services of The Arkansas Department of Human Services;

Defendants-Appellants,

Arkansas Foundation for Medical Care;
Defendant,

Roy Jeffus, in his official capacity as Interim Director of Arkansas Department of Human Services Division of Medical Services;

Defendant-Appellant.

Before SMITH, HEANEY, and BENTON, Circuit Judges.

OPINION

HEANEY, Circuit Judge.

The issue presented in this appeal is whether the district court erred by ordering the Arkansas Department of Human Services (ADHS) and the Arkansas Foundation for Medical Care (AFMC) to publish to Medicaid service beneficiaries and providers the identity of physician reviewers who make decisions to approve or deny medical care to Medicaid-eligible children. Because the district court's order is at odds with the relevant Medicaid regulations, we reverse.

BACKGROUND

The general background to this case is detailed in our prior decisions in *Pediatric Speciality Care, Inc., v. Arkansas Department of Human Services*, 293 F.3d 472 (8th Cir. 2002); *Pediatric Specialty Care, Inc. v. Arkansas Department of Human Services*, 364 F.3d 925 (8th Cir. 2004); and *Pediatric Specialty Care, Inc. v. Arkansas Department of Human Services*, 443 F.3d 1005, 2006 U.S. App. LEXIS 9564, No. 05-1668, issued today. In short, this case stems

from ADHS's attempts to curtail the services it provides to needy children in Arkansas pursuant to the Medicaid Act. ADHS contracts with AFMC to review applications for Medicaid services and to determine whether and to what extent applicants qualify for those services. The plaintiffs are applicants for Medicaid services, both as recipients and providers. They contend that ADHS and AFMC manipulate their system of prior authorization so as to deny medically necessary services to qualified, Medicaid-eligible children solely for the state's financial benefit.

As relevant to this appeal, one of the plaintiffs in this matter, Tomorrow's Child Learning Center, LLC, moved the district court for a temporary restraining order requiring AFMC (and, consequently, ADHS) to disclose to Medicaid service recipients and providers the names of the physician reviewers who made determinations regarding whether and to what extent children were eligible for treatment. By order dated May 28, 2004, the court treated this motion as one for a preliminary injunction and denied the motion, holding that such disclosure was prohibited by applicable Medicaid Act provisions and regulations. Several months later, the district court informed the parties that it was reconsidering its earlier decision and solicited letter briefs on the matter. On November 29, 2004, the court issued an order reversing its May 28, 2004 decision. In the decision, the court held that the plaintiffs "may discover the name, qualifications, and identity of each peer review physician and advisor who participated in the denial of medical benefits, based on the premise that the care did not meet medical necessity requirements," but that the plaintiffs "may not discover any patient records of non-parties, nor may Plaintiffs discover any material produced by [AFMC] that evaluated the failure of a particular medical provider to follow professional standards of care." (Dist. Ct. Order of Nov. 29, 2004 at 15.) This appeal followed.

ANALYSIS

"We review a district court's grant or denial of preliminary injunctive relief for an abuse of discretion or misplaced reliance on an erroneous legal principle." *Goff v. Harper*, 60 F.3d 518, 520 (8th Cir. 1995). This is a "deferential standard," only permitting us to reverse the district court if, "after a thorough review of the record, the proof unmistakably establishes clear error or an abuse of discretion." *FTC v. Freeman Hosp.*, 69 F.3d 260, 267 (8th Cir. 1995).

Ordinarily, the district court is to consider four factors in deciding whether to issue the preliminary injunction: (1) the threat of irreparable harm, (2) the balance between that harm and the injury to the non-moving party if the injunction is granted, (3) the probability of success on the merits of the claim, and (4) whether granting the injunction would benefit the public interest. *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981) (en banc).

AFMC and ADHS assert that the district court's order must be reversed because it conflicts with provisions of the Medicaid Act, as well as regulations interpreting the Act that protect the confidentiality of peer reviewers. The plaintiffs argue that the district court's order is not a final appealable matter, because the district court did not explicitly go through a *Dataphase* analysis. We disagree, and thus undertake analysis of whether the order was properly issued. *Accord Baker Elec. Co-Op, Inc. v. Chaske*, 28 F.3d 1466, 1472 (8th Cir. 1994) (characterizing a temporary restraining order as a preliminary injunction and undertaking a *Dataphase* analysis even though the district court failed to do so).

Pursuant to 42 U.S.C. § 1320c-9(a), data and information collected by a peer review organization such as AFMC "shall be held in confidence and shall not be disclosed," except in very limited circumstances. "No patient record in the possession of [a peer review organization] shall be subject to subpoena or discovery proceedings in a civil action." § 1320c-9(d). The statute states more specifically that information reviewed by a peer review organization in order to determine if the provider's quality of care meets professional standards is privileged from discovery. *Id.* (referencing §§ 1320c-3(a)(1)(B) and 1320c-5(a)(2)).

The Department of Health & Human Services (HHS) is charged by statute with the authority to promulgate regulations regarding the confidentiality of patient records held by peer review organizations. Those regulations must "assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care." 42 U.S.C. § 1320c-9(a)(2). HHS has issued such regulations, which interpret what information is subject to disclosure and what information is confidential. The regulations deem information confidential if it "explicitly or implicitly identifies an individual patient, practitioner, *or reviewer*," and all peer review deliberations. 42 C.F.R. § 480.101(b) (emphasis added). The regulation defines peer review deliberations to include "review notes, minutes of meetings and any other records of discussions and judgments involving matters regarding [peer review] responsibilities and appeals from [peer review organization] determinations, in which the opinions of, or judgment about, a particular individual or institution can be discerned." § 480.101(b)(4). Peer review organizations generally may not disclose confidential information, subject to limited exceptions. *See generally* 42 C.F.R. §§ 480.130-480.143 (regulations regarding disclosure of confidential information).

Within the regulations concerning disclosure of confidential information, it is stated that a peer review organization "must not disclose its deliberations," except to federal governmental agencies such as the Centers for Medicare and Medicaid Services, the Office of the Inspector General, or the General Accounting Office. 42 C.F.R. § 480.139(a)(1). The regulations further state that a peer review organization may only disclose "information on a particular practitioner or reviewer at the written request of or with the written consent of that practitioner or reviewer." 42 C.F.R. § 480.133(a)(2)(iii).

Taken together, these regulations do not permit the disclosure ordered by the district court. They indicate clearly that: (1) nearly all peer review organization information is confidential; (2) confidential information related to deliberations must not be disclosed, except in circumstances not presented here; and (3) physician reviewer identities may be disclosed, but only with the reviewer's written consent. Thus, it seems clear under the regulations that the information plaintiffs seek--the identities of physician reviewers in specific cases--is not subject to discovery.

The plaintiffs have not argued, nor do we see any reason why, these regulations are not entitled to deference. *See Chevron U.S.A. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984). The district court cited *Public Citizen, Inc. v. United States Department of Health & Human Services*, 357 U.S. App. D.C. 1, 332 F.3d 654 (D.C. Cir. 2003), in support of the view that we need not follow the agency's confidentiality regulations. There, the court refused to grant *Chevron* deference to the confidentiality regulations for a section of the Medicaid Act that was enacted after the regulations were promulgated. *Pub. Citizen*, 332 F.3d at 659.

We agree with the proposition that where regulations precede enactment of the statute, they cannot possibly be read as interpreting the statute. That is not the situation before us, however. Since § 42 U.S.C. § 1320c-9's most recent amendment, HHS has reconsidered and amended the confidentiality provisions of its regulations, such that information could now be disclosed with the written consent of a medical practitioner or peer reviewer. *See* 69 Fed. Reg. 48916, 49266-67 (Aug. 11, 2004) (amending 42 C.F.R. §§ 480.133, 480.140). Thus, unlike *Public Citizen*, the confidentiality regulations at issue here have been significantly and materially changed subsequent to the statute's amendment.

According the regulations the deference required by *Chevron*, we find the interpretation to be "based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. The statute governing disclosure specifically charges HHS with the duty to ensure peer review information is kept confidential through regulations aimed toward protecting "the rights and interests of patients, health care practitioners, [and] providers of health care." 42 U.S.C. § 1320c-9(a)(2). The regulations effectuate that purpose, as they allow disclosure of the identities of peer reviewers only after obtaining written consent of the peer reviewer. 42 C.F.R. § 480.133(a)(2)(iii). While the plaintiffs may disagree with HHS's regulation, it is permissible and thus must stand.

CONCLUSION

The district court's order compelling disclosure of the identities of peer reviewers conflicts with the applicable enforceable regulations. For this reason, we have no alternative but to reverse.

APPENDIX C

IN THE UNITED STATE DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS—
WESTERN DIVISION

NO. 4:01 CV00830 WRW

[Filed November 29, 2004]

PEDIATRIC SPECIALTY CARE, INC., ET AL PLAINTIFFS	)
vs.	)
ARKANSAS DEPARTMENT OF HUMAN SERVICES, ET AL DEFENDANTS	)

ORDER

On May 28, 2004, an order was entered in this case addressing several pending motions, including a Motion by Plaintiff seeking an Order to compel or enjoin Defendants to reveal the names of peer reviewers responsible for determining when and whether services are medically necessary (Docket No. 150). Against my initial instinct that "secret doctors" should not be allowed to deny medical care when Medicaid beneficiaries could not effectively challenge the denial, I found that 42 U.S.C. § 1320c-9 clothed the deliberations of peer review organizations (PRO) with a

statutory privilege against the formal discovery process in any administrative or civil proceeding. On reflection, I tentatively changed my mind, but before entering this Order, I asked the parties to file letter briefs on the subject. After reviewing the Defendant's arguments, I am convinced that the original Order addressing this issue was wrong.

Background

Due to the complexity of the laws and regulations in this case, background information is necessary. In 1982, Congress amended the Social Security Act by enacting the "Peer Review Improvement Act," codified as 42 U.S.C. § 1320c, et seq. The 1982 legislation allowed PROs to assume responsibility for the review of health care services funded under Medicare; to determine if those services are medically necessary, efficient, effective; and if they meet professionally recognized standards of care. The amended statute also contained a number of confidentiality provisions that are in 42 U.S.C. § 1320c-9. These generally prohibit the disclosure of information acquired or produced by a PRO in carrying out its functions under its contracts with the Department of Human Services (DHS). At the time the Act was amended, Congress also authorized the Secretary of Health and Human Services to create additional regulations addressing the confidentiality provision. The pertinent regulations were originally promulgated in 1985 and have not significantly changed since that time. *See* 42 CFR §§ 476.101-133 (1985) and 42 CFR §§ 480.101-133 (2002). Unfortunately, the names of these organizations change often, and what were referred to as peer review organizations (PROs) are now called quality improvement organizations (QIOs). To avoid any further confusion, I will continue to use the old moniker, PRO.

By amending the Act as codified in § 1320c-9, and by limiting the formal discovery process in civil litigation, Congress created a statutory privilege with respect to certain information in the possession of, or produced by, PROs. In their letter brief, the Department of Human Services (DHS) claims that "nothing in Federal law authorizes the disclosure sought by plaintiffs." As stated above, I now disagree.

Plaintiffs do not have to prove that disclosure of evidence in a civil or administrative action is "authorized." The DHS must show that the disclosure is protected by a privilege. Privileges are not generally favored by federal courts and are narrowly construed so that access to truth will not be unnecessarily fettered. The general rule is that "the public has a right to every man's evidence." *Trammel v. United States,* 445 U.S. (1980)(quoting *United States v. Bryan,* 339 U.S. 323, 331 (1950)), Any infringements on the "predominant principle of utilizing all rational means for ascertaining the truth," are to be strictly construed. *Jaffee v. Redmond,* 518 U.S. 1, 9 (1996); *University of Pa., v. Equal Employment Opportunity Com'n* , 493 U.S. 182 at 189 (1990). Tensions arise in the law of privileges when the public benefit of keeping certain information confidential conflicts with the public benefit of ascertaining the truth of a matter through the disclosure of all relevant information. *See Trammel,* 445 U.S. at 50, 100 S.Ct. 906; *University of Pa,* 493 U.S. 182 at 189; *Jaffee,* 518 U.S. at 9. The United States Supreme Court summed up the guiding rule succinctly: "[A]n asserted privilege must serve the public ends." *Upjohn v. United States,* 449 U.S. 383, 389 (1981). Thus, to recognize a matter as privileged is to find that its concealment promotes an important public interest that outweighs the need for evidence. *See Trammel,* 445 U.S. at 51. These principles are manifested in 42 U.S.C. § 1320c-9(d). The language of this subsection of the Act is unambiguous, and establishes what matters are and

are not protected from formal discovery process. It is also clear that this section was promulgated by Congress to distinguish the formal discovery process -- together with the traditional subpoena power[1]-- from FOI requests and other discovery avenues provided to the general public. In other words, this section applies to individuals who are either parties to lawsuits or are pursuing administrative remedies.

Section 1320c-9(d) reads:

(d) Subpoena and discovery proceedings regarding patient records

No patient record in the possession of an organization having a contract with the Secretary under this part shall be subject to subpoena or discovery proceedings in a civil action. No document or other information produced by such an organization in connection with its deliberations in making determinations under section *1320c-3(a)(1)(B) or 1320c-5(a)(2)* of this title shall be subject to subpoena or discovery in any administrative or civil proceeding; except that such an organization shall provide, upon request of a practitioner or other person adversely affected by such a determination, a summary of the organization's

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[1] The Compulsory Process Clause confers the right to compel witnesses to appear through use of subpoena power. The right to compel a witness's presence in the courtroom could not protect the integrity of the adversary process if it did not embrace the right to have the witness's testimony heard by the trier of fact. The right to offer testimony is thus grounded in the Sixth Amendment even though it is not described in so many words. *U.S. v. Janis* 2004 WL 2421999, 5 (8th Cir. 2004)

findings and conclusions in making the determination. 42 U.S.C. § 1320c-9 (Emphasis added)

There are two types of documents protected under subsection (d) of § 1320c-9: 1) patient records in possession of the PRO; 2) records produced by the PRO containing information about its deliberations that specifically deal with matters outlined in subsection 1320c-3(a)(1)(B) and subsection 1320c-5(a)(2). Patient records are addressed in the first sentence of subsection 1320c-9(d), while materials other than patient records are addressed in the second sentence. I will discuss these two types of information separately, starting first where subsection (d) begins -- *patient records*.

Discussion

The DHS argues that the term "patient records" means any patient information connected exclusively with medical necessity determinations. This is not what the sentence says, instead it refers to "patient records in possession of the PRO". 42 U.S.C. 1320c-9(d). Peer review organizations have custody and control of individual patient records for a variety of reasons, not just for medical necessity determinations.

Defendant DHS, also claims that the term *patient records* includes records that disclose the identity of any PRO physician who makes medical necessity decisions. In other words, Defendant has redefined patient records to include medical records of individuals under medical necessity review, and any documents revealing the name of the physicians responsible for medical necessity reviews. This interpretation is overly broad.

Statutory interpretation starts with the language of the statute itself; and a statute is read applying the "ordinary,

contemporary and common meaning" of the words used. *Perrin v. United States,* 444 U.S. 37, 42 (1979). A patient record is a medical record generated by a treating physician for treatment and diagnosis. This is the common and ordinary usage of this term. In fact, Federal Regulations routinely interchange the terms "medical records" and "patient records" in rules designed to protect *patient* privacy.[2] In short, there is no indication that Congress meant to embellish the common sense definition of "patient records" in the manner suggested by Defendant.

Further, the first sentence of subsection 1320c-9(d) describes documents created by entities other than PROs, because it clearly refers to records in the *"possession of"* these organizations. By contrast, there is no reference to records *"created, produced or generated"* by the PRO. Applying common usage and common sense to the wording of the first sentence, I find that the term *patient records* includes medical records of treating physicians, not records created by reviewing physicians working for a PRO.

Medical or patient records generally contain private information and are owed protection. However, there is no specific federal privilege protecting the confidentiality of medical records in federal cases. Federal Rule of Evidence 501 does not recognize a physician-patient (or hospital-patient) privilege. Rule 501 makes federal common law the source of any privileges in federal-question suits unless an Act of Congress provides otherwise. *Northwestern Memorial Hosp. v. Ashcroft,* 362 F.3d 923, (7th Cir. 2004). Congress

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[2] *See* 38 CFR §1.489; 38 CFR §17.81-82; 38 CFR §403.730; 42 CFR §403.730; §416.47; 42 CFR §482.13; 42 CFR §482.24; 42 CFR §486.306; 42 CFR §489.24.

would have no need to pass a law to protect a litigant's own medical records from discovery for the obvious reason that the patient-party could secure her own records simply by going to the source without resorting to serving costly subpoenas on PROs.

While a patient may secure her own records, she should not be allowed to gain access to the medical records of others because the records may be relevant to her pending lawsuit. This is the public policy rationale for the first sentence of subsection 1320c-9(d). It is designed to prevent parties to civil actions from getting non-party patient records in order to advance a theory of liability or to buttress a claim or defense to a civil action.

If, on the other hand, I were to adopt a more expansive interpretation of subsection 1320c-9(d) -- and find that the term *patient records* exempts from discovery all documents that are possessed by a PRO as well as produced by PRO physicians during a review process-- then there would have been no need for Congress to draft the second sentence carving out an additional privilege. Such an expansive reading would prohibit any litigant at any time, from determining what goes on during the review process of a PRO. In other words, Congress would have created a Star Chamber of the Medicare-Medicaid process.

However, Congress drafted a second sentence that is more specific in the creation of an additional privilege. In other words, the second sentence in § 1320c-9(d) sets out what materials in addition to patient records are privileged. An overly broad construction of the terminology in the first sentence would render the second sentence superfluous. In statutory construction, where specific expressions conflict with general ones, the rule is to give greater effect to the

specific expression. *See Reeder-Simco GMC, Inc. v. Volvo GM Heavy Truck Corp.* 374 F.3d 701,716 (8th Cir. 2004); Sutherland Statutory Construction § 51.05, at 499-500 (N. Singer ed. 1984). At the very least, specific expressions should inform an interpretation of general expressions. An expansive construction of the first sentence of § 1320c-9(d) would create a privilege protecting from disclosure all documents as well as the identity of all physicians connected to PROs. I have reviewed federal case law and have discovered that when faced with similar questions, federal courts are reluctant to recognize a broad privilege applicable to peer review organizations.[3] Because I decline to accept the interpretation of the first sentence suggested by DHS, an examination of the more specific second sentence of subsection 1320c-9(d) is now in order.

The second sentence precludes discovery of information described in two other subsections of the Amended Act. These are § 1320c-3(a)(l)(B) and § 1320c-5(a)(2). In order to better understand the intent of Congress, it is important to review both subsections in context. I will begin with the § 1320c-3(a):

> (a) Review of professional activities, determinations of review authority; consultation with professional health

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[3] *University of Pa.*, 493 U.S. at 195; *Virmani v. Novant Health, Inc.*, 259 F.3d 284 (4th Cir. 2001); *Memorial Hosp. For McHenry County*, 664 F.2d 1058 (7th Cir. 1981); *Leon v. County of San Diego*, 202 F.R.D. 631 (S.D. Cal, 2001); *Nilavar, M.D. v. Mercy Health System-Western Ohio*, 210 F.R.D. 597 (S.D. Ohio, 2002); *Public Citizen, Inc. v. U.S. Dept. Of Health and Human Services*, 332 F.3d 654 (D.C. Cir., 2003); *Atteberry v. Longmont United Hospital*, 221 F.R.D. 644 (D. Col. 2004).

care practitioners, standards of health care; other duties ....

> (1) The organization shall review some or all of the professional activities in the area, subject to the terms of the contract and subject to the requirements of subsection (d) of this section, of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made... for the purpose of determining whether-
>
> > (A) such services and items are or were reasonable and medically necessary and whether such services and items are not allowable under subsection (a)(1) or (a)(9) of section 1395y of this title;
> >
> > *(B) the quality of such services meets professionally recognized standards of health care; and*
> >
> > (C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type. 42U.S.C § 1320c-3(a) (Emphasis added).

Clearly, placing § 1320c-3(a)(1)(B) in context shows that there are two other categories listed in subsection (A) and (C)

which have been *excluded* from the privilege created in § 1320c-9(d). These excluded materials are: (1) documents gathered for the purpose of making a medical necessity determination; and (2) information gathered to determine feasibility of outpatient versus inpatient care. On the other hand, Congress specifically included information gathered by a PRO to determine whether medical providers meet recognized "standards of care." 42 U.S.C.§ 1320c-3(a)(1)(B).

This brings me to a consideration of § 1320c-5(a) and a review of the entire subsection:

> (a) Assurances regarding services and items ordered or provided by practitioner or provider
>
> It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) ... to assure, to the extent of his authority that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this chapter--
>
> (1) will be provided economically and only when, and to the extent, medically necessary;
>
> (2) *will be of a quality which meets professionally recognized standards of health care; and*
>
> (3) will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities. 42 U.S.C.A. § 1320c-5(a) (Emphasis added).

Again, there are two additional categories of information outlined in this subsection that are *not* privileged. These two categories are set out in subsections (1) and (3) and address information gathered to determine medical necessity and the efficacy of the evidence supporting medical necessity. The privileged information set out in subsection (2) is information gathered to determine if medical providers meet recognized "standards of care." 42 U.S.C.§ 1320c-5(a)(2):

Both § 1320c-3(a) and § 1320c-5(a) list three categories of information that a PRO may gather. Only *one* of these categories of information is designated as privileged by §1320c-9(d). The category involves *standard of care* inquiries. The pertinent language of §1320 (a)(1)(B) refers to information that the care provided by the physician is "of a quality which meets professionally recognized standards of health care." Likewise, the pertinent language of § 1320c-5(a)(2) refers to information that the care provided by the physician is "of a quality which meets professionally recognized standards of health care." When a physician fails to provide care that meets recognized standards, he or she has committed malpractice.[4] The use of the phrase *standard of care* makes it clear that this category of information concerns negligence inquiries.

There are two other categories of information that are excluded from the privilege conferred by § 1320c-9(d), and include information gathered for medical necessity and feasibility. See above § 1320c-3(a)(1) (A) and (C); § 1320c-5(a) (1) and (3). I can only conclude that Congress did not intend to protect these categories of information from

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[4] ARKANSAS MODEL JURY INSTRUCTIONS, Instruction 1501 (1999); *Dewitt v. Brown,* 669 F.2d 516 (8th Cir. Ark. 1982)

disclosure, else Congress would have listed them. It follows that Congress intended for information within these two categories to be non-privileged. It is sound statutory construction that the express designation of one thing may properly be construed to mean the exclusion of another. Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion. *INS v.* Cardoza-Fonseca, 480 U.S. 421, 432, (1987). *See also Singh-Kaur v. Ashcroft* 385 F.3d 293, 299 (3rd Cir. 2004)

Subsections (A) and (C) of § 1320c-3 and (1) and (3) of § 1320c-5 refer to information gathered by PROs for the purpose of determining that care is medically necessary, is economically effective, and is supported by evidence of medical necessity and quality. In sum, the second sentence in 1320c-9(d) protects from disclosure any investigative material associated with findings of possible medical negligence. Such a protection from disclosure would conform with numerous state laws which protect peer review evaluations made for the purpose of investigating possible malpractice.[5] The public interest at play here is the need to encourage peer review committees to evaluate candidly a provider's competence or lack thereof, so safety issues may be addressed and corrected for the public good. Congress determined that such public interest is important enough to outweigh the need for

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[5] *See* Ark. Code. Ann. § 25 - 19- 105(a) *et seq.* (Supp. 1995); Ark.Code.Ann. § 16-46-105 (Repl.1994)(provides that peer review and quality assurance records shall not be subject to discovery or admissible in any legal proceeding and shall be absolutely privileged communications.); *Berry v. Saline Memorial Hosp.*, 322 Ark. 182 (Ark.,1995)

evidence, and therefore, justified the creation of a privilege. *Trammel,* 455 U.S. at 51.

The case repeatedly cited by Defendants in this matter is *Armstrong v. Dwyer,* 155 F.3d 211 (3rd Cir. 1998). The *Armstrong* case involved a medical malpractice investigation made by a PRO on behalf of the DHS. The plaintiff in *Armstrong* was seeking material from the PRO that investigated the defendant physician's care of the plaintiff. The court applied the specific language of § 1320c-9 and held that such materials were privileged.

However, the facts presented in *Armstrong* are clearly distinguishable from a Medicare-Medicaid beneficiary pursing a civil action requesting material from the PRO which denied benefits based on medical necessity. As I have explained above, Congress specifically allows disclosure of such material by excluding it from the list of material protected in the second sentence of § 1320c-9(d). The first sentence is not applicable in this situation because the patient records belong to the beneficiary challenging the denial, and the plaintiffs would not have to obtain their own medical records from the PRO, since plaintiffs have a right to those records.

Defendant, Arkansas Foundation for Medical Care (AFMC) bases its argument on regulations enacted by the Secretary of Health and Human Services. AFMC begins its argument by quoting 42 U.S.C. § 1320c-3(a)(9)(A), which authorizes the Secretary to permit access to any information *"subject to the provisions of 1320c-9 of this title."* I agree. Any regulations must be consistent with the intent of Congress as set forth in the statute itself.

In two cogent opinions from the District of Columbia Circuit, the District Court and Circuit Court refused to accept

the Defendant's broad interpretation of the Peer Review Improvement Act as evidenced in the PRO manual created by the Department of Human Services. *Public Citizen, Inc. v. Department of Health and Human Service, et al.* 151 F.Supp.2d 64 (D.C.D.C.2001) *aff'd* 332 F.3d 654 (D.C. Cir. 2003). Instead the District Court ordered the Department to provide a litigant with substantive information contained in a peer review investigation. The District Court pointed out-- and the Circuit Court agreed-- that when a statute is clear and unambiguous, consideration of administrative interpretation contrary to such language is inappropriate, *Id.* at 151 F. Supp. 70; 332 F.3d 659 (citing *Chevron U.S.A. Inc. v. Natural Resources Defense Council,* 467 U.S. 837, 104 S.Ct. 2778 (1984)).

Defendant, AFMC cites 42 CFR § 480.139 (b) (1) which forbids the disclosure of QIO (PRO) deliberations and the identity of the physicians, advisors and consultants involved in deliberations. However, the preceding regulation, 42 CFR § 480.138 (b) (1), sets forth the application of the regulation. First, confidential material in medical necessity determinations are only mentioned in relation to investigations by state and federal licensing agencies who are studying the patterns of certain practitioners. Again, this is applicable to professional standards inquiries.

Second, 42 CFR § 430.138(b) (1) states that restrictions on disclosures are not *applicable "in the course of administrative hearings held under the Social Security Act."* Finally, 42 CFR § 480.138(b)(2) states in pertinent part that "[A] QIO must disclose information regarding QIO deliberations and *quality* review study information only as specified in 42 CFR § 480.139" (Emphasis added). Once again, the words medical necessity are absent. This, I believe, is an eloquent silence. It follows that this exclusion means that

42 CFR § 480.139 applies to *quality* reviews, not *medical* necessity reviews, except to the extent that medical necessity materials reveal patterns of professional conduct or misconduct.

AFMC strenuously argues that the identity of physicians and others who take part in PRO deliberations are absolutely protected from a formal discovery process by the above cited regulation. As stated, the regulations must be consistent with the intent expressed by Congress as unambiguously set out in § 1320c-9. I have read this section of the Peer Review Improvement Act carefully. There is nothing in the language of § 1320c-9 that demonstrates an intent to protect the confidentiality of PRO physicians and advisors. In fact, § 1320c-9(a)(2) declares its general purpose is to insure the confidentiality of the following PRO material: "[A]ny data or information acquired by any such organization in the exercise of its duties and functions shall be held in confidence and shall not be disclosed to any person." Again, I point out that the use of the term "acquired" and the absence of the term "produced" is significant. The word produced only appears in subsection 1320c-9(d), addressing *standard of care* investigations, which I have already discussed.

Most importantly, Congress gives the Secretary the right to create exceptions to any limitations imposed by § 1320c-9, but Congress does not give the Secretary the power to expand the Act. The Act requires the Secretary to formulate regulations so that exceptions to the confidentiality rule may be created for the following reasons:

> (1) to the extent that may be necessary to carry out the purposes of this part,

> (2) in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests *of patients, health care practitioners, or providers of health care.* (emphasis added)

A close reading of subsection (a)(2), quoted above, indicates that Congress was interested in protecting the privacy and interests of patients, health care practitioners, and other health care providers–not members of PRO organizations. The court in the *Public Citizen* case agrees that the Secretary's role with regard to non-disclosure is not expansive:

> [But] § 1320c-9(a)(2) does not permit the Secretary to impose his own non-disclosure requirements; rather, it authorizes the Secretary to promulgate regulatory *exceptions* to the general non-disclosure requirement. *Public Citizen, Inc.*, 332 F.3d at 664.

Although the level of deference afforded an agency interpretation is high, courts remain the final authority in matters of statutory interpretation and must reject administrative constructions which are contrary to clear congressional intent. *Ragsdale v. Wolverine Worldwide Inc.*, 218 F.3d 933, 936 (8th 2000). In the instant case, I do not find that the regulation relied on by the AFMC to be necessarily in conflict with § 1320c-9. The conflict arises only if I accept AFMC's interpretation of the regulation, and I do not. Instead, I find that 42 C.F.R. § 480.138, limits the application of 42 CFR § 480.139 to quality investigations that are concerned with possible safety issues involving departures from standard of care, and licensing of practitioners.

Conclusion

In view of the above, I find that Plaintiffs may utilize all formal discovery tools provided by the Federal Rules of Civil Procedure. Consequently, Plaintiffs may discover the name, qualifications, and identity of each peer review physician and advisor who participated in the denial of medical benefits, based on the premise that the care did not meet medical necessity requirements.

Further, the Plaintiffs may discover any other relevant material produced by the PRO in making medical necessity determination in their case. On the other hand, consistent with the intent of § 1320c-9 (d), Plaintiffs may not discover any patient records of non-parties, nor may Plaintiffs discover any material produced by the PRO that evaluated the failure of a particular medical provider to follow professional standards of care.

IT IS SO ORDERED this 29th day of November, 2004

/s/
UNITED STATES DISTRICT JUDGE
WM. R. WILSON, JR.

APPENDIX D

42 U.S.C. § 1320c-3. Functions of peer review organizations

(a) Review of professional activities; determination of payment; determination of review authority; consultation with professional health care practitioners; standards of health care; other duties. Any utilization and quality control peer review organization entering into a contract with the Secretary under this part must perform the following functions:

(1) The organization shall review some or all of the professional activities in the area, subject to the terms of the contract and subject to the requirements of subsection (d), of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under title XVIII (including where payment is made for such services to eligible organizations pursuant to contracts under section 1876, to Medicare Advantage organizations pursuant to contracts under part C, and to prescription drug sponsors pursuant to contracts under part D) for the purpose of determining whether--

(A) such services and items are or were reasonable and medically necessary and whether such services and items are not allowable under subsection (a)(1) or (a)(9) of section 1862;

(B) the quality of such services meets professionally recognized standards of health care; and

(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an

inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

If the organization performs such reviews with respect to a type of health care practitioner other than medical doctors, the organization shall establish procedures for the involvement of health care practitioners of that type in such reviews.

(2) The organization shall determine, on the basis of the review carried out under subparagraphs (A), (B), and (C) of paragraph (1), whether payment shall be made for services under title XVIII. Such determination shall constitute the conclusive determination on those issues for purposes of payment under title XVIII, except that payment may be made if--

(A) such payment is allowed by reason of section 1879;

(B) in the case of inpatient hospital services or posthospital extended care services, the peer review organization determines that additional time is required in order to arrange for postdischarge care, but payment may be continued under this subparagraph for not more than two days, but only in the case where the provider of such services did not know and could not reasonably have been expected to know (as determined under section 1879) that payment would not otherwise be made for such services under title XVIII prior to notification by the organization under paragraph (3);

(C) such determination is changed as the result of any hearing or review of the determination under section 1155; or

(D) such payment is authorized under section 1861(v)(1)(G).

The organization shall identify cases for which payment should not be made by reason of paragraph (1)(B) only

through the use of criteria developed pursuant to guidelines established by the Secretary.

(3) (A) Subject to subparagraphs (B) and (D), whenever the organization makes a determination that any health care services or items furnished or to be furnished to a patient by any practitioner or provider are disapproved, the organization shall promptly notify such patient and the agency or organization responsible for the payment of claims under title XVIII of this Act of such determination.

(B) The notification under subparagraph (A) with respect to services or items disapproved by reason of subparagraph (A) or (C) of paragraph (1) shall not occur until 20 days after the date that the organization has--

(i) made a preliminary notification to such practitioner or provider of such proposed determination, and

(ii) provided such practitioner or provider an opportunity for discussion and review of the proposed determination.

(C) The discussion and review conducted under subparagraph (B)(ii) shall not affect the rights of a practitioner or provider to a formal reconsideration of a determination under this part (as provided under section 1155).

(D) The notification under subparagraph (A) with respect to services or items disapproved by reason of paragraph (1)(B) shall not occur until after--

(i) the organization has notified the practitioner or provider involved of the determination and of the practitioner's or provider's right to a formal reconsideration of the determination under section 1155, and

(ii) if the provider or practitioner requests such a reconsideration, the organization has made such a reconsideration.

If a provider or practitioner is provided a reconsideration, such reconsideration shall be in lieu of any subsequent reconsideration to which the provider or practitioner may be

otherwise entitled under section 1155, but shall not affect the right of a beneficiary from seeking reconsideration under such section of the organization's determination (after any reconsideration requested by the provider or physician under clause (ii)).

(E) (i) In the case of services and items provided by a physician that were disapproved by reason of paragraph (1)(B), the notice to the patient shall state the following: "In the judgment of the peer review organization, the medical care received was not acceptable under the medicare program. The reasons for the denial have been discussed with your physician.".

(ii) In the case of services or items provided by an entity or practitioner other than a physician, the Secretary may substitute the entity or practitioner which provided the services or items for the term "physician" in the notice described in clause (i).

(4) (A) The organization shall, after consultation with the Secretary, determine the types and kinds of cases (whether by type of health care or diagnosis involved, or whether in terms of other relevant criteria relating to the provision of health care services) with respect to which such organization will, in order to most effectively carry out the purposes of this part, exercise review authority under the contract. The organization shall notify the Secretary periodically with respect to such determinations. Each peer review organization shall provide that a reasonable proportion of its activities are involved with reviewing, under paragraph (1)(B), the quality of services and that a reasonable allocation of such activities is made among the different cases and settings (including post-acute-care settings, ambulatory settings, and health maintenance organizations). In establishing such allocation, the organization shall consider (i) whether there is reason to believe that there is a particular need for reviews of particular cases or settings because of previous problems regarding

quality of care, (ii) the cost of such reviews and the likely yield of such reviews in terms of number and seriousness of quality of care problems likely to be discovered as a result of such reviews, and (iii) the availability and adequacy of alternative quality review and assurance mechanisms.

(B) **[Caution: For applicability of 1990 amendment, see § 4358(c) of Act Nov. 5, 1990, P.L. 101-508, which appears as a note to this section.]** The contract of each organization shall provide for the review of services (including both inpatient and outpatient services) provided by eligible organizations pursuant to a risk sharing contract under section 1876 (or that is subject to review under section 1882(t)(3)) for the purpose of determining whether the quality of such services meets professionally recognized standards of health care, including whether appropriate health care services have not been provided or have been provided in inappropriate settings and whether individuals enrolled with an eligible organization have adequate access to health care services provided by or through such organization (as determined, in part, by a survey of individuals enrolled with the organization who have not yet used the organization to receive such services). The contract of each organization shall also provide that with respect to health care provided by a health maintenance organization or competitive medical plan under section 1876, the organization shall maintain a beneficiary outreach program designed to apprise individuals receiving care under such section of the role of the peer review system, of the rights of the individual under such system, and of the method and purposes for contacting the organization. The previous two sentences shall not apply with respect to a contract year if another entity has been awarded a contract under subparagraph (C). Under the contract the level of effort expended by the organization on reviews under this subparagraph shall be equivalent, on a per enrollee basis, to the level of effort expended by the organization on

utilization and quality reviews performed with respect to individuals not enrolled with an eligible organization.

(C) The Secretary may provide, by contract under competitive procurement procedures on a State-by-State basis in up to 25 States, for the review described in subparagraph (B) by an appropriate entity (which may be a peer review organization described in that subparagraph). In selecting among States in which to conduct such competitive procurement procedures, the Secretary may not select States which, as a group, have more than 50 percent of the total number of individuals enrolled with eligible organizations under section 1876. Under a contract with an entity under this subparagraph--

(i) the entity must be, or must meet all the requirements under section 1152 to be, a utilization and quality control peer review organization (other than the ability to perform review functions under this section that are not described in subparagraph (B)),

(ii) the contract must meet the requirement of section 1153(b)(3), and

(iii) the level of effort expended under the contract shall be, to the extent practicable, not less than the level of effort that would otherwise be required under the third sentence of subparagraph (B) if this subparagraph did not apply.

(5) The organization shall consult with nurses and other professional health care practitioners (other than physicians described in section 1861(r)(1) and with representatives of institutional and noninstitutional providers of health care services, with respect to the organization's responsibility for the review under paragraph (1) of the professional activities of such practitioners and providers.

(6) (A) The organization shall, consistent with the provisions of its contract under this part, apply professionally developed norms of care, diagnosis, and treatment based upon

typical patterns of practice within the geographic area served by the organization as principal points of evaluation and review, taking into consideration national norms where appropriate. Such norms with respect to treatment for particular illnesses or health conditions shall include--

(i) the types and extent of the health care services which, taking into account differing, but acceptable, modes of treatment and methods of organizing and delivering care, are considered within the range of appropriate diagnosis and treatment of such illness or health condition, consistent with professionally recognized and accepted patterns of care; and

(ii) the type of health care facility which is considered, consistent with such standards, to be the type in which health care services which are medically appropriate for such illness or condition can most economically be provided.

As a component of the norms described in clause (i) or (ii), the organization shall take into account the special problems associated with delivering care in remote rural areas, the availability of service alternatives to inpatient hospitalization, and other appropriate factors (such as the distance from a patient's residence to the site of care, family support, availability of proximate alternative sites of care, and the patient's ability to carry out necessary or prescribed self-care regimens) that could adversely affect the safety or effectiveness of treatment provided on an outpatient basis.

(B) The organization shall--

(i) offer to provide, several times each year, for a physician representing the organization to meet (at a hospital or at a regional meeting) with medical and administrative staff of each hospital (the services of which are reviewed by the organization) respecting the organization's review of the hospital's services for which payment may be made under title XVIII, and

(ii) publish (not less often than annually) and distribute to providers and practitioners whose services are subject to review a report that describes the organization's findings with respect to the types of cases in which the organization has frequently determined that (I) inappropriate or unnecessary care has been provided, (II) services were rendered in an inappropriate setting, or (III) services did not meet professionally recognized standards of health care.

(7) The organization, to the extent necessary and appropriate to the performance of the contract, shall--

(A) (i) make arrangements to utilize the services of persons who are practitioners of, or specialists in, the various areas of medicine (including dentistry, optometry, and podiatry), or other types of health care, which persons shall, to the maximum extent practicable, be individuals engaged in the practice of their profession within the area served by such organization; and

(ii) in the case of psychiatric and physical rehabilitation services, make arrangements to ensure that (to the extent possible) initial review of such services be made by a physician who is trained in psychiatry or physical rehabilitation (as appropriate).

(B) undertake such professional inquiries either before or after, or both before and after, the provision of services with respect to which such organization has a responsibility for review which in the judgment of such organization will facilitate its activities;

(C) examine the pertinent records of any practitioner or provider of health care services providing services with respect to which such organization has a responsibility for review under paragraph (1); and

(D) inspect the facilities in which care is rendered or services are provided (which are located in such area) of any practitioner or provider of health care services providing

services with respect to which such organization has a responsibility for review under paragraph (1).

(8) The organization shall perform such duties and functions and assume such responsibilities and comply with such other requirements as may be required by this part or under regulations of the Secretary promulgated to carry out the provisions of this part or as may be required to carry out section 1862(a)(15).

(9) (A) The organization shall collect such information relevant to its functions, and keep and maintain such records, in such form as the Secretary may require to carry out the purposes of this part, and shall permit access to and use of any such information and records as the Secretary may require for such purposes, subject to the provisions of section 1160.

(B) If the organization finds, after reasonable notice to and opportunity for discussion with the physician or practitioner concerned, that the physician or practitioner has furnished services in violation of section 1156(a) and the organization determines that the physician or practitioner should enter into a corrective action plan under section 1156(b)(1), the organization shall notify the State board or boards responsible for the licensing or disciplining of the physician or practitioner of its finding and of any action taken as a result of the finding.

(10) The organization shall coordinate activities, including information exchanges, which are consistent with economical and efficient operation of programs among appropriate public and private agencies or organizations including--

(A) agencies under contract pursuant to sections 1816 and 1842 of this Act;

(B) other peer review organizations having contracts under this part; and

(C) other public or private review organizations as may be appropriate.

(11) The organization shall make available its facilities and resources for contracting with private and public entities paying for health care in its area for review, as feasible and appropriate, of services reimbursed by such entities.

(12) [Deleted]

(13) Notwithstanding paragraph (4), the organization shall perform the review described in paragraph (1) with respect to early readmission cases to determine if the previous inpatient hospital services and the post-hospital services met professionally recognized standards of health care. Such reviews may be performed on a sample basis if the organization and the Secretary determine it to be appropriate. In this paragraph, an "early readmission case" is a case in which an individual, after discharge from a hospital, is readmitted to a hospital less than 31 days after the date of the most recent previous discharge.

(14) The organization shall conduct an appropriate review of all written complaints about the quality of services (for which payment may otherwise be made under title XVIII) not meeting professionally recognized standards of health care, if the complaint is filed with the organization by an individual entitled to benefits for such services under such title (or a person acting on the individual's behalf). The organization shall inform the individual (or representative) of the organization's final disposition of the complaint. Before the organization concludes that the quality of services does not meet professionally recognized standards of health care, the organization must provide the practitioner or person concerned with reasonable notice and opportunity for discussion.

(15) During each year of the contract entered into under section 1153(b), the organization shall perform significant on-site review activities, including on-site review in at least 20 percent of the rural hospitals in the organization's area.

(16) The organization shall provide for a review and report to the Secretary when requested by the Secretary under section 1867(d)(3). The organization shall provide reasonable notice of the review to the physician and hospital involved. Within the time period permitted by the Secretary, the organization shall provide a reasonable opportunity for discussion with the physician and hospital involved, and an opportunity for the physician and hospital to submit additional information, before issuing its report to the Secretary under such section.

(17) The organization shall execute its responsibilities under subparagraphs (A) and (B) of paragraph (1) by offering to providers, practitioners, Medicare Advantage organizations offering Medicare Advantage plans under part C, and prescription drug sponsors offering prescription drug plans under part D quality improvement assistance pertaining to prescription drug therapy. For purposes of this part and title XVIII, the functions described in this paragraph shall be treated as a review function.

(b) Review by physicians; physician's family defined.

(1) No physicians shall be permitted to review--

(A) health care services provided to a patient if he was directly responsible for providing such services; or

(B) health care services provided in or by an institution, organization, or agency, if he or any member of his family has, directly or indirectly, a significant financial interest in such institution, organization, or agency.

(2) For purposes of this subsection, a physician's family includes only his spouse (other than a spouse who is legally separated from him under a decree of divorce or separate maintenance), children (including legally adopted children), grandchildren, parents, and grandparents.

(c) Utilization of services of physicians to make final determinations of denial decisions with respect to the professional conduct of other physicians. No utilization and quality control peer review organization shall utilize the services of any individual who is not a duly licensed doctor of medicine, osteopathy, dentistry, optometry, or podiatry to make final determinations of denial decisions in accordance with its duties and functions under this part with respect to the professional conduct of any other duly licensed doctor of medicine, osteopathy, dentistry, optometry, or podiatry, or any act performed by any duly licensed doctor of medicine, osteopathy, dentistry, optometry, or podiatry in the exercise of his profession.

(d) Review of ambulatory surgical procedures. Each contract under this part shall require that the utilization and quality control peer review organization's review responsibility pursuant to subsection (a)(1) will include review of all ambulatory surgical procedures specified pursuant to section 1833(i)(1)(A) which are performed in the area, or, at the discretion of the Secretary a sample of such procedures.

(e) Review of hospital denial notices.

(1) If--

(A) a hospital has determined that a patient no longer requires inpatient hospital care, and

(B) the attending physician has agreed with the hospital's determination, the hospital may provide the patient (or the patient's representative) with a notice (meeting conditions prescribed by the Secretary under section 1879) of the determination.

(2)--(5) [Deleted]

(f) Identification of methods for identifying cases of substandard care. The Secretary, in consultation with

appropriate experts, shall identify methods that would be available to assist peer review organizations (under subsection (a)(4)) in identifying those cases which are more likely than others to be associated with a quality of services which does not meet professionally recognized standards of health care.

42 U.S.C. § 1320c-5. Obligations of health care practitioners and providers of health care services; sanctions and penalties; hearings and review

(a) Assurances regarding services and items ordered or provided by practitioner or provider. It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this Act, to assure, to the extent of his authority that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this Act--

(1) will be provided economically and only when, and to the extent, medically necessary;

(2) will be of a quality which meets professionally recognized standards of health care; and

(3) will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities.

(b) Sanctions and penalties; hearings and review.

(1) If after reasonable notice and opportunity for discussion with the practitioner or person concerned, and, if appropriate, after the practitioner or person has been given a reasonable opportunity to enter into and complete a corrective action plan (which may include remedial education) agreed to

by the organization, and has failed successfully to complete such plan, any organization having a contract with the Secretary under this part determines that such practitioner or person has--

(A) failed in a substantial number of cases substantially to comply with any obligation imposed on him under subsection (a), or

(B) grossly and flagrantly violated any such obligation in one or more instances, such organization shall submit a report and recommendations to the Secretary. If the Secretary agrees with such determination, the Secretary (in addition to any other sanction provided under law) may exclude (permanently or for such period as the Secretary may prescribe, except that such period may not be less than 1 year) such practitioner or person from eligibility to provide services under this Act on a reimbursable basis. If the Secretary fails to act upon the recommendations submitted to him by such organization within 120 days after such submission, such practitioner or person shall be excluded from eligibility to provide services on a reimbursable basis until such time as the Secretary determines otherwise.

(2) A determination made by the Secretary under this subsection to exclude a practitioner or person shall be effective on the same date and in the same manner as an exclusion from participation under the programs under this Act becomes effective under section 1128(c), and shall (subject to the minimum period specified in the second sentence of paragraph (1)) remain in effect until the Secretary finds and gives reasonable notice to the public that the basis for such determination has been removed and that there is reasonable assurance that it will not recur.

(3) In lieu of the sanction authorized by paragraph (1), the Secretary may require that (as a condition to the continued eligibility of such practitioner or person to provide such health care services on a reimbursable basis) such practitioner or

person pays [pay] to the United States, in case such acts or conduct involved the provision or ordering by such practitioner or person of health care services which were medically improper or unnecessary, an amount not in excess of up to $10,000 for each instance of the medically improper or unnecessary services so provided. Such amount may be deducted from any sums owing by the United States (or any instrumentality thereof) to the practitioner or person from whom such amount is claimed.

(4) Any practitioner or person furnishing services described in paragraph (1) who is dissatisfied with a determination made by the Secretary under this subsection shall be entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g).

(5) Before the Secretary may effect an exclusion under paragraph (2) in the case of a provider or practitioner located in a rural health professional shortage area or in a county with a population of less than 70,000, the provider or practitioner adversely affected by the determination is entitled to a hearing before an administrative law judge (described in section 205(b)) respecting whether the provider or practitioner should be able to continue furnishing services to individuals entitled to benefits under this Act, pending completion of the administrative review procedure under paragraph (4). If the judge does not determine, by a preponderance of the evidence, that the provider or practitioner will pose a serious risk to such individuals if permitted to continue furnishing such services, the Secretary shall not effect the exclusion under paragraph (2) until the provider or practitioner has been provided reasonable notice and opportunity for an administrative hearing thereon under paragraph (4).

(6) When the Secretary effects an exclusion of a physician under paragraph (2), the Secretary shall notify the State board responsible for the licensing of the physician of the exclusion.

(c) Enlistment of support of other organizations to assure practitioner's or provider's compliance with obligations. It shall be the duty of each utilization and quality control peer review organization to use such authority or influence it may possess as a professional organization, and to enlist the support of any other professional or governmental organization having influence or authority over health care practitioners and any other person (including a hospital or other health care facility, organization, or agency) providing health care services in the area served by such review organization, in assuring that each practitioner or person (referred to in subsection (a)) providing health care services in such area shall comply with all obligations imposed on him under subsection (a).

42 U.S.C. § 1320c-9. Prohibition against disclosure of information

(a) Freedom of Information Act inapplicable; exceptions to nondisclosure. An organization, in carrying out its functions under a contract entered into under this part, shall not be a Federal agency for purposes of the provisions of section 552 of title 5, United States Code (commonly referred to as the Freedom of Information Act). Any data or information acquired by any such organization in the exercise of its duties and functions shall be held in confidence and shall not be disclosed to any person except--

(1) to the extent that may be necessary to carry out the purposes of this part,

(2) in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care, or

(3) in accordance with subsection (b).

(b) Disclosure of information permitted. An organization having a contract with the Secretary under this part shall provide in accordance with procedures and safeguards established by the Secretary, data and information--

(1) which may identify specific providers or practitioners as may be necessary--

(A) to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse, which data and information shall be provided by the peer review organization to any such agency at the request of such agency relating to a specific case or pattern;

(B) to assist appropriate Federal and State agencies recognized by the Secretary as having responsibility for identifying cases or patterns involving risks to the public health, which data and information shall be provided by the peer review organization to any such agency--

(i) at the discretion of the peer review organization, at the request of such agency relating to a specific case or pattern with respect to which such agency has made a finding, or has a reasonable belief, that there may be a substantial risk to the public health, or

(ii) upon a finding by, or the reasonable belief of, the peer review organization that there may be a substantial risk to the public health;

(C) to assist appropriate State agencies recognized by the Secretary as having responsibility for licensing or certification of providers or practitioners or to assist national accreditation bodies acting pursuant to section 1865 in

accrediting providers for purposes of meeting the conditions described in title XVIII, which data and information shall be provided by the peer review organization to any such agency or body at the request of such agency or body relating to a specific case or to a possible pattern of substandard care, but only to the extent that such data and information are required by the agency or body to carry out its respective function which is within the jurisdiction of the agency or body under State law or under section 1865; and

(D) to provide notice in accordance with section 1154(a)(9)(B);

(2) to assist the Secretary, and such Federal and State agencies recognized by the Secretary as having health planning or related responsibilities under Federal or State law (including health systems agencies and State health planning and development agencies), in carrying out appropriate health care planning and related activities, which data and information shall be provided in such format and manner as may be prescribed by the Secretary or agreed upon by the responsible Federal and State agencies and such organization, and shall be in the form of aggregate statistical data (without explicitly identifying any individual) on a geographic, institutional, or other basis reflecting the volume and frequency of services furnished, as well as the demographic characteristics of the population subject to review by such organization.

The penalty provided in subsection (c) shall not apply to the disclosure of any information received under this subsection, except that such penalty shall apply to the disclosure (by the agency receiving such information) of any such information described in paragraph (1) unless such disclosure is made in a judicial, administrative, or other formal legal proceeding resulting from an investigation conducted by the agency receiving the information. An organization may require payment of a reasonable fee for

providing information under this subsection in response to a request for such information.

(c) Penalties. It shall be unlawful for any person to disclose any such information described in subsection (a) other than for the purposes provided in subsections (a) and (b), and any person violating the provisions of this section shall, upon conviction, be fined not more than $1,000, and imprisoned for not more than 6 months, or both, and shall be required to pay the costs of prosecution.

(d) Subpoena and discovery proceedings regarding patient records. No patient record in the possession of an organization having a contract with the Secretary under this part shall be subject to subpoena or discovery proceedings in a civil action. No document or other information produced by such an organization in connection with its deliberations in making determinations under section 1154(a)(1)(B) or 1156(a)(2) shall be subject to subpoena or discovery in any administrative or civil proceeding; except that such an organization shall provide, upon request of a practitioner or other person adversely affected by such a determination, a summary of the organization's findings and conclusions in making the determination.

(e) Organizations with contracts. For purposes of this section and section 1157, the term "organization with a contract with the Secretary under this part" includes an entity with a contract with the Secretary under section 1154(a)(4)(C).

APPENDIX E

42 C.F.R. § 480.101 Scope and definitions.

(a) Scope. This subpart sets forth the policies and procedures governing --

(1) Disclosure of information collected, acquired or generated by a Utilization and Quality Control Quality Improvement Organization (QIO) (or the review component of a QIO subcontractor) in performance of its responsibilities under the Act and these regulations; and

(2) Acquisition and maintenance of information by a QIO to comply with its responsibilities under the Act.

(b) Definitions. As used in this part:

Abuse means any unlawful conduct relating to items or services for which payment is sought under Title XVIII of the Act.

Aggregate statistical data means any utilization, admission, discharge or diagnostic related group (DRG) data arrayed on a geographic, institutional or other basis in which the volume and frequency of services are shown without identifying any individual.

Confidential information means any of the following:

(1) Information that explicitly or implicitly identifies an individual patient, practitioner or reviewer.

(2) Sanction reports and recommendations.

(3) Quality review studies which identify patients, practitioners or institutions.

(4) QIO deliberations.

Health care facility or facility means an organization involved in the delivery of health care services or items for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Implicitly identify(ies) means data so unique or numbers so small so that identification of an individual patient, practitioners or reviewer would be obvious.

Non-facility organization means a corporate entity that: (1) Is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities in the QIO area.

Patient representative means -- (1) an individual designated by the patient, in writing, as authorized to request and receive QIO information that would otherwise be disclosable to that patient; or (2) an individual identified by the QIO in accordance with § 480.132(c)(3) when the beneficiary is mentally, physically or legally unable to designate a representative.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

QIO deliberations means discussions or communications (within a QIO or between a QIO and a QIO subcontractor) including, but not limited to, review notes, minutes of meetings and any other records of discussions and judgments involving review matters regarding QIO review responsibilities and appeals from QIO determinations, in which the opinions of, or judgment about, a particular individual or institution can be discerned.

QIO information means any data or information collected, acquired or generated by a QIO in the exercise of its duties and functions under Title XI Part B or Title XVIII of the Act.

QIO interpretations and generalizations on the quality of health care means an assessment of the quality of care furnished by an individual provider or group of providers based on the QIO's knowledge of the area gained from its medical review experience (e.g., quality review studies) and any other information obtained through the QIO's review activities.

QIO review system means the QIO and those organizations and individuals who either assist the QIO or are directly responsible for providing medical care or for making determinations with respect to the medical necessity, appropriate level and quality of health care services that may be reimbursed under the Act. The system includes --

(1) The QIO and its officers, members and employees;

(2) QIO subcontractors;

(3) Health care institutions and practitioners whose services are reviewed;

(4) QIO reviewers and supporting staff; and

(5) Data support organizations.

Public information means information which has been disclosed to the public.

Quality review study means an assessment, conducted by or for a QIO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

Quality review study information means all documentation related to the quality review study process.

Reviewer means review coordinator, physician, or other person authorized to perform QIO review functions.

Sanction report means a report filed pursuant to section 1156 of the Act and part 474 of this chapter documenting the QIO's determination that a practitioner or institution has failed to meet obligations imposed by section 1156 of the Act.

Shared health data system means an agency or other entity authorized by Federal or State law that is used by the QIO review system to provide information or to conduct or arrange for the collection, processing, and dissemination of information on health care services.

Subcontractor means a facility or a non-facility organization under contract with a QIO to perform QIO review functions.